K004010

APR 2 6 2001

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Luann Ochs, M.S.

Date Prepared: December 22, 2000

2) Device name

Proprietary name: Accu-Chek Compact™ System

Common name: Whole blood glucose test system

Classification name: 75, LFR, Glucose dehydrogenase, glucose

3) Predicate device

We claim substantial equivalence to the Accu-Chek Simplicity system, K972876 and K993829.

4) Device Description

The Accu-Chek Compact system utilizes reagent test strips housed within a test drum. The test drum is inserted into the meter. Upon pressing a button, the user is presented with a test strip. Blood is applied to the end of the test strip, and a glucose result is reported.

The test principle is:
Step 1: Glucose is oxidized by the PQQ-dependent enzyme glucose-dye-oxidoreductase (EC.1.1.99.17) to gluconolactone and the reduction equivalents are transferred to the enzyme bound PQQ to give $PQQH_2$.
Step 2: The enzyme transfers the reduction equivalents from $PQQH_2$ to the oxidized form of the mediator. Bis-(2-hydroxyethyl)-(4-hydrox-iminocyclohexa-2,5-dienylidene)-ammonium chloride is used as mediator.
Step 3: The reduced form of the mediator reduces the indicator 2,18-phosphomolybdic acid to produce the color of heteropolyblue.

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5) Intended use

The Accu-Chek Compact system is intended for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities.

6) Comparison to predicate device

The Roche Diagnostics Accu-Chek Compact system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Accu-Chek Simplicity System.

Similarities to predicate device

The Accu-Chek Compact system is similar to the Accu-Chek Simplicity system in the following ways:

Topic	Comment
Intended Use	Both systems are intended for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities.
Closed System	Each systems' test strips and controls are designed to be used only with that system.
Sample Types	Both systems utilize whole blood samples, capillary or venous, only.
Home and Professional use	Both systems are intended to be used by persons in their home, or by health care professionals in health care facilities.
Operating principle	Step 1: Glucose from the whole blood sample is oxidized by the PQQ-dependent enzyme glucose-dye-oxidoreductase to gluconolactone and the reduction equivalents are transferred to the enzyme bound PQQ to give $PQQH_2$. Step 2: The enzyme transfers the reduction equivalents from $PQQH_2$ to the oxidized form of the mediator bis-(2-hydroxyethyl)-(4-hydroximinocyclohexa-2,5-dienylidene)-ammonium chloride. Step 3: The reduced form of the mediator reduces the indicator 2,18-phosphomolybdic acid to produce the color of heteropolyblue.
Reagent test strips	Both systems utilize reagent test strips manufactured with the same reactive ingredients.

Test strip storage conditions	Both systems require the test strips to be stored at room temperature between +36°F and +86°F (10 - 40°C). Do not freeze.
Test strip operating conditions	Both systems operate at temperatures between 50°F and 104°F, and less than 85% humidity.
Sample volume	Both systems require a minimum sample of 3.5 µL.
Quality control procedure	Quality controls are tested when the meter displays "CTRL", if the cap is left off the vial of test strips (drum), when a new vial is opened, if the meter is dropped, if the result does not agree with the way the user feels, whenever the user wishes to check the performance of the system.
Labeling instructions regarding expected results	Both systems state: The normal fasting adult blood glucose range for a non-diabetic is 70 – 105 mg/dL. One to two hours after meals, normal blood glucose levels should be less than 140 mg/dL. Doctors will determine the range that is appropriate for their individual patients.
Labeling instructions regarding response to unusual results	Both systems instruct the user to run a quality control test, if the result is outside the acceptable QC recovery range, contact Roche Diagnostic's Accu-Chek Customer Care Center; if result is within the acceptable range, review proper testing procedure and repeat blood glucose test with a new test strip.
Reportable range	Both systems have reportable ranges of 10 – 600 mg/dL
Warnings and precautions	Both systems are for *in vitro* diagnostic use only.
Reagent composition	Reagent ingredients for both systems are: Glucose – dye-oxidoreductase Bis-(2-hydroxyethyl)-(4-hydroximinocyclohexa-2,5-dienylidene)-ammonium chloride 2,18-Phosphomolybdic acid Stabilizer Non-reactive substances.

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Differences from predicate device

The Accu-Chek Compact system and the Accu-Chek Simplicity system differ in the following ways:

Topic	Accu-Chek Compact	Accu-Chek Simplicity
Test strip packaging	Test strips are conveniently housed within a test drum that is inserted into the meter. It is not necessary for the user to carry vials of test strips. Each test drum contains seventeen test strips. Test drums are packaged either in individual vials, or 3 test drums per vial.	Strips are available in two packaging configurations: 50 test strips in a vial, or 100 test strips in a vial. Strips are removed from the vial individually, and inserted into the meter.
Monitor coding procedure	The code is automatically read from the test drum upon insertion of the test drum into the meter.	A code key, included in the test strip vial, is inserted in the meter.
Test procedure	Step 1: Press the blue button. A test strip is automatically presented by the meter. Step 2: Touch the drop of blood to the notch at the end of the test strip. Read result.	Step 1: With the meter turned on, insert a test strip with the green pad facing up and arrows pointing toward meter until it locks into place. Step 2: Apply a drop of blood to top of green test pad. Read result.
Test strip storage	Test strips in the vial are stable until the expiration date. Once the test drum is removed from the vial, the test strips within the test drum remain stable for 90 days.	Test strips are stored in the vial, and are stable until the expiration date.

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Benefits

Accu-Chek Compact's new test drum packaging configuration is convenient and easy-to-use. Its look, feel, and handling resembles a 35mm film cartridge.

Accu-Chek Compact's new reagent test drum design also allows for the addition of several new test strip failsafes:

- The Accu-Chek Compact meter checks the integrity of each test strip prior to use. Strips that have been exposed to excessive heat or humidity are not used to generate test results.
- The meter automatically locks out the user after the test drum has been inside the meter for 90 days.
- Users don't have to remember to code their system, coding is performed automatically whenever a test drum is inserted into the meter.

Performance characteristics

The following chart shows a comparison of performance characteristic claims for the Accu-Chek Compact system and the Accu-Chek Simplicity system.

Claim	Accu-Chek Simplicity system (Predicate)	Accu-Chek Compact system (New device)
Precision with controls	Level 1 Level 2	Low Mid High
Mean	84.0 196.4	58.9 127.3 227.7
SD	2.0	1.0
CV	2.5	2.7 2.4
Precision with whole blood	Level 1 Level 2 Level 3	Low Mid High
Mean	28.7 129.4 499	56 140 390
SD	1.2	1.4
CV	3.0 3.4	1.9 3.0
Accuracy – capillary blood	Comparison to hexokinase glucose reference N = 202 y = 1.02x + 2.6 r = 0.989 range = 51 to 490 mg/dL	Comparison to hexokinase glucose reference N = 138 y = 0.954X + 1.8 r = 0.992 range = 64 – 350 mg/dL
Accuracy – consumer study	Comparison to hexokinase glucose reference N = 134 y = 1.082x – 2.9 r = 0.976 Range = 58 to 357 mg/dL	Comparison to hexokinase glucose reference N = 138 y = 0.956x + 2.0 r = 0.994 Range = 63 - 359

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 6 2001

Ms. Luann Ochs, M.S.
Regulatory Program Manager
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: 510(k) NUMBER: K004010
Trade/Device Name: Accu-Chek Compact System
Regulation Number: 862.1345
Regulatory Class: II
Product Code: LFR
Dated: March 21, 2001
Received: March 22, 2001

Dear Ms. Ochs:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K004010
Device Name: Accu-Chek Compact System
Indications for Use:

The Accu-Chek Compact System is intended for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K004010

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)